

Appln. No. 10/586,141
Amd. dated June 28, 2010
Reply to Office Action of March 26, 2010

REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1-3 and 5-8 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

New claim 6 is based on claim 1 and step d) of claim 6 finds support in the present specification at page 9, lines 26-31. New claim 7 is based on claim 1 as well as on steps 1-4 and 6 disclosed in the Example in the present specification. New claim 8 is supported by the present specification at page 8, lines 13-14, and in Figure 1.

Claim 3 has been objected to because *E. coli* is not written in italics. This objection is obviated by the amendment to claim 3 to recite the full name of *Escherichia coli* in italics.

Reconsideration and withdrawal of the objection are therefore respectfully requested.

Claims 1-5 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is obviated by the amendment to claim 1 to recite the steps present in the prior art and to which the improvement provided by the present invention is a Reverse Phase Chromatography step between

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the step of solubilization of the aggregated proteins in inclusion bodies/denaturation and the step of renaturation/refolding, both steps now having antecedent basis in the claim.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claim 5 has been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with both the written description requirement and the enablement requirement. Both rejections are obviated by the amendment to claim 5 to positively recite that the chemokine is the mutant protein having the sequence of SEQ ID NO:1, as supported at page 10, lines 10-13 of the specification.

Reconsideration and withdrawal of the §112, first paragraph, rejections are therefore respectfully requested.

Claims 1-3 have been rejected under 35 U.S.C. §102(b) as being anticipated by Musacchio et al. (1996). This rejection is respectfully traversed.

Musacchio is directed to a process for isolating meningococcal Opc protein, expressed in *E. coli* as inclusion bodies, where the recombinant protein is solubilized and eluted through Reverse Phase Chromatography before being refolded. However, Musacchio does not disclose a process for recovering a chemokine protein. As meningococcal Opc protein is not a

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chemokine, Musacchio cannot anticipate the presently claimed invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claim 1-5 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Musacchio et al. (1996) in view of Li et al. (WO 98/14467) and Proudfoot et al. (WO 02/28419). This rejection is respectfully traversed.

The disclosure and teachings of Musacchio are discussed above. The secondary Li reference discloses methods for solubilizing and purifying the proteins, such as chemokines, expressed in insoluble form (i.e., in inclusion bodies), as well as for refolding proteins that have been solubilized. The secondary Proudfoot reference relates only to mutants of CC chemokines with Example 16 showing the expression and purification of RANTES mutants in *E. coli*.

From a reading of Musacchio, it is not obvious to one of ordinary skill in the art that reverse phase chromatography used for a meningococcal Opc protein could be applied to chemokines prior to a refolding step and still achieve high yields and high purity. Accordingly, one of ordinary skill in the art would not be led to the presently claimed process by the

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combination of disclosures and teachings from Musacchio, Li and Proudfoot.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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